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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Taeyoung Yoon

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EXAMINER

MURRAY, JEFFREY H

ART UNIT

PAPER NUMBER

1624

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/811,359	<b>Applicant(s)</b> YOON ET AL.	
	<b>Examiner</b> JEFFREY H. MURRAY	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-22,30,35,39-64,67 and 69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 67 is/are allowed.
- 6) ☒ Claim(s) 1,3-22,30,35 is/are rejected.
- 7) ☒ Claim(s) 39-64 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1, 3-22, 30, 35, 39-64 and 69 are rejected.
2. Claims 1, 3-22, 30, 35, 39-64 and 69 are pending in this application. This action is in response to the applicants' amendment after a non-final and reply filed on November 21, 2007.

### ***Status of Rejections***

3. Claims 1, 3-22, 30, 35, 39-64 and 69 54-107 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The arguments made by the applicants have not been found persuasive, and thus the rejection of Claims 1, 3-22, 30, 35, 39-64 and 69 54-107 is upheld.
4. Claim 1 is rejected under 35 U.S.C. 102(b), as failing the novelty requirement within a claim. The rejection to the claim is hereby withdrawn in view of applicants' arguments o the claim's novelty.
5. Claims 3, 5, 15, and 16 are rejected under 35 U.S.C. 102(b), as failing the novelty requirement within a claim. The rejection to the claims is hereby withdrawn in view of applicants' arguments o the claim's novelty.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

***New Objections***

***Claim Objections***

6. Applicant is advised that should claim 1 be found allowable, claim 30 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***New/Upheld Rejections***

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

7. Claims 1, 3-22, 30, and 35 are still rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds of the formula I where R<sup>1</sup> is an alkoxy group; R<sup>2</sup> is a disubstituted amino group; R<sup>3</sup> is an optionally substituted alkyl group and Ar is a phenyl group optionally substituted 1 to 3 times with either a methyl group or an optionally substituted alkoxy group, does not reasonably provide enablement for compounds or compositions where the R and Ar variables are other than those stated above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

8. The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation. (*United States v. Teletronics Inc.*, 8 USPQ2d

1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based on a single factor, but rather a conclusion reached by weighing many factors (See *Ex parte Forman* 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988)).

1) *Amount of guidance provided by Applicant.* Applicant has provided no guidance, examples, or provided any chemical or biological data and/or testing results of any compounds of Formula I where the compounds or compositions are other than the R and Ar groups previously mentioned. Applicant has only shown a select number of compounds or compositions within the specification and of these, none of the compounds or compositions falls outside of the scope of enablement mentioned herein.

2) *Unpredictability in the art.* Chemistry is unpredictable. See *In Re Marzocchi* and *Horton* 169 USPQ at 367 paragraph 3:

"Most non-chemists would probably be horrified if they were to learn how many attempted syntheses fail, and how inefficient research chemists are. The ratio of successful to unsuccessful chemical experiments in a normal research laboratory is far below unity, and synthetic research chemists, in the same way as most scientists, spend most of their time working out what went wrong, and why. Despite the many pitfalls lurking in organic synthesis, most organic chemistry textbooks and research articles do give the impression that organic reactions just proceed smoothly and that the total synthesis of complex natural products, for instance, is maybe a labor-intensive but otherwise undemanding task. In fact, most syntheses of structurally complex natural products are the result of several years of hard work by a team of chemists, with almost every step requiring careful optimization. The final synthesis usually looks quite different from that originally planned, because of unexpected difficulties encountered in the initially chosen synthetic sequence. Only the seasoned practitioner who has experienced for himself the many failures and frustrations which the development (sometimes even the repetition) of a synthesis usually implies will be able to appraise such work .....Chemists tend not to publish negative results, because these are, as opposed to positive results, never definite (and far too copious)" Dorwald F. A. *Side Reactions in Organic*

*Synthesis*, 2005, Wiley: VCH, Weinheim pg. IX of Preface.

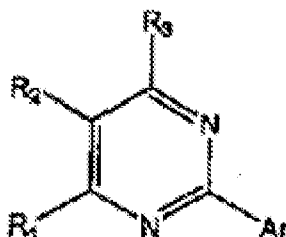
The scope of any compounds where the R variables are not those previously described above is not adequately enabled or defined. Applicants have provided no guidance as how the compounds are made more active *in vivo*.

3) *Number of working examples*. Applicant has provided no working examples of any compounds or compositions where the R variables are other than those described above. "Specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims. *Markush* claims must be provided with support in the disclosure for each member of the *Markush* group. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula." See MPEP 608.01(p).

4) *Nature of the invention*. The application concerns some novel substituted arylpyrimidine compounds that bind with high selectivity and/or high affinity to CRF 1 receptors (Corticotropin Releasing Factor 1 Receptors). This invention also relates to pharmaceutical compositions comprising such compounds and to the use of such compounds in treatment of psychiatric disorders and neurological diseases, including major depression, anxiety-related disorders, post-traumatic stress disorder, supranuclear palsy and feeding disorders, as well as treatment of immunological, cardiovascular or heart-related diseases and colonic hypersensitivity associated with

psychopathological disturbance and stress. Additionally this invention relates to the use such compounds as probes for the localization of CRF1 receptors in cells and tissues.

5) *Scope of the Claims.* The scope of the claims is all of the tens of thousands of compounds represented by general formula I:



thus the scope of the claims is very broad.

6) *Level of skill in the art.* The artisan using Applicants invention would be a chemist with a M.S. or Ph.D. degree, and having several years of bench experience.

MPEP §2164.01 (a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here that Applicant is not enabled for making these compounds or compositions.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

***Claim Rejections - 35 USC § 112***

9. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. The recitation of an intended use, chemical activity, or functional description of some "additional" property for a compound (or moiety/functionality attached to a chemical core) or a composition containing same in a dependent claim, must result in a tangible structural difference between the product and of the independent claim and the product set forth in the dependent claim. In the absence of said structural difference between the product of the independent claim and that of the dependent claim, said dependent claim is seen to be a substantial duplicate, and said recitation is not afforded critical weight and fails to further limit the product in said dependent claim. In the instant set of claims, claim 30 fails to further limit the claim to compounds from which they depend.

11. Claim 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. In this case the referencing of the binding assays and example 99a do not comply with 35 U.S.C. § 112, 2<sup>nd</sup> paragraph. See *Ex Parte Fressola* 27 USPQ2d 1608:

“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. Claims in utility applications <sup>1</sup> that define the invention entirely by reference to the specification and/or drawings, so-called “omnibus” or “formal” claims, while perhaps once accepted in American patent practice, are properly rejected under Section 112 Para. 2



Art Unit: 1624

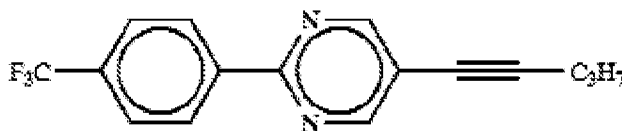
as failing to particularly point out and distinctly claim the invention. See MPEP Section 706.03(h) (5th ed., rev. 14, Nov. 1992); Landis, Mechanics of Patent Claim Drafting, Section 2 (1974). This analysis is limited to claims in utility applications. Plant patent claims are defined "in formal terms to the plant shown and described." Claims in design patents are recited in formal terms to the ornamental design "as shown" or, where there is a properly included special description of the design, the ornamental design "as shown and described." MPEP Section 1503.01.....The general rule is that the claims should be self-contained; that is, they should not expressly rely upon the description or drawing to give them meaning. . . . The terms "substantially as described" and the like, once much used in claims (GLASCOCK 1943 Section 5640) are now rarely seen. The Office disregards them in interpreting claims. . . . Claims consisting only in a reference to the disclosure, as "The features of novelty herein disclosed," are not allowed except in design cases.....A claim which refers to the specification defeats the purpose of a claim."

The claims should be self-contained and self-referential.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

### ***Claim Rejections - 35 USC § 102***

12. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Lewis et. al., U.S. Patent No. 5,986,096. Several compounds within the patent anticipate the current claim 1. The compound:

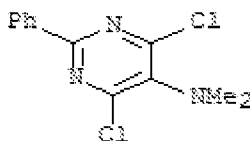


reads on Claim 1 by having a pyrimidine ring substituted in the 2-position by Ar where Ar is a 4-trifluoromethylphenyl group, R<sup>1</sup> and R<sup>3</sup> are hydrogen and R<sup>2</sup> is an alkynyl group which is optionally substituted with an alkyl group.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

***Allowable Subject Matter***

13. Claim 69 is allowed.
14. Claims 39-64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
15. Claims 39-64 and 69 are considered allowable because the closet prior art, Brunner, et. al., EP 112280, teaches the following compound:



Which is a pyrimidine ring substituted where R<sup>1</sup> and R<sup>3</sup> are substituted by halogens, R<sup>2</sup> is a dimethylamino group, and the 2-position is substituted by an Ar where Ar is a phenyl group. The closest prior art however, fails to teach any compounds or composition where the phenyl group mono-, di-, or tri-substituted.

***Conclusion***

16. Claims 1, 3-22, 30, 35 are rejected.
17. Claims 39-64 are objected.
18. Claim 69 is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is 571-272-9023. The examiner can normally be reached on Mon.-Thurs. 7:30-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey H Murray/  
Patent Examiner  
Art Unit 1624

**/James O. Wilson/  
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